

# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,157	09/19/2003	Kenneth W. Whitley	P-5655/5	7091
26253 75	90 01/23/2006		EXAMINER	
	IGHET, VP AND CHI	BOWERS, NATHAN ANDREW		
BECTON, DICKINSON AND COMPANY 1 BECTON DRIVE, MC 110 FRANKLIN LAKES, NJ 07417-1880			ART UNIT	PAPER NUMBER
			1744	

DATE MAILED: 01/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)			
Office Action Summary						
		10/666,157	WHITLEY, KENNETH W.			
	Office Action Cummary	Examiner	Art Unit			
	The MAILING DATE of this communication app	Nathan A. Bowers	1744			
Period fo		sears on the cover sheet with the c	orrespondence address			
WHIC - Exter after - If NO - Failu Any r	CRTENED STATUTORY PERIOD FOR REPLICATION OF THE MAILING DISSIONS of time may be available under the provisions of 37 CFR 1.1 SIX (6) MONTHS from the mailing date of this communication. Period for reply is specified above, the maximum statutory period to reply within the set or extended period for reply will, by statute eply received by the Office later than three months after the mailing digital patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be timwill apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	N. hely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status						
1)⊠	Responsive to communication(s) filed on 19 S	eptember 2003.				
2a) <u></u> □	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.					
3)□	·					
	closed in accordance with the practice under E	Ex parte Quayle, 1935 C.D. 11, 45	33 O.G. 213.			
Dispositi	on of Claims					
5)□ 6)⊠ 7)□	Claim(s) <u>1-20</u> is/are pending in the application 4a) Of the above claim(s) is/are withdra Claim(s) is/are allowed. Claim(s) <u>1-14</u> is/are rejected. Claim(s) is/are objected to. Claim(s) <u>15-20</u> are subject to restriction and/o	wn from consideration.				
Applicati	on Papers					
10)⊠	The specification is objected to by the Examine The drawing(s) filed on 19 September 2003 is Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Example 1.	are: a) $\boxtimes$ accepted or b) $\square$ objec drawing(s) be held in abeyance. See tion is required if the drawing(s) is obj	e 37 CFR 1.85(a). lected to. See 37 CFR 1.121(d).			
Priority u	ınder 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachmen	·	_				
2) Notice	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) r No(s)/Mail Date <u>010804</u> .	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:				

### **DETAILED ACTION**

### Election/Restrictions

- 1) Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - Claims 1-14, drawn to a stackable container, classified in class 206, subclass 509.
  - II. Claims 15-20, drawn to a method of culturing cells, classified in class 435, subclass 298.2.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group II and Group I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e). In this case the apparatus can be used in a number of additional applications besides cell culturing. The stackable container as claimed could be used to accommodate essentially any chemical or biological fluid, and facilitate a plurality of different reactions. The container could be used to store any industrial fluid, water sample, or beverage.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Nanette Thomas on 06 January 2006 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-14. Affirmation of the election must be made by applicant in replying to this Office action. Claims 15-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the free required under 37 CFR 1.17(i).

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 2) Claims 1 and 4-9 rejected under 35 U.S.C. 102(e) as being anticipated by Pedmo (US 6585123).

With respect to claims 1, 4, and 5, Pedmo discloses a container comprising an elongate cylindrical wall having a closed bottom end and an opposed projecting neck portion defining a liquid opening. This is disclosed in column 2, lines 15-38. The closed

Application/Control Number: 10/666,157 Page 4

Art Unit: 1744

bottom end includes an inwardly directed recessed portion for accommodating a neck portion end of an adjacent stacked similar container. This is shown in Figure 4 and disclosed in column 3, lines 24-25. The recessed portion includes a planar surface having at least one rib (Figure 5:34) extending therefrom for defining a space between the neck portion of the similar container and the bottom of the original container. The container is disclosed generally as a bottle, but could inherently be used to provide a controlled environment for cell growth culturing. The ribs are integral with the planar surface, and the recessed portion further includes side walls.

With respect to claims 6 and 7, Pedmo discloses the container in claim 5, wherein a plurality of ribs (Figure 5:34) is provided, and the ribs are equally spaced about the longitudinal axis of the container. This is disclosed in column 2, lines 46-58.

With respect to claims 8 and 9, Pedmo discloses the container in claim 1, wherein the recessed portion is generally frustoconical in shape, and the neck includes integral external screw threads for receiving an internally screw threaded cap thereon. This is apparent from the Figures.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3) Claims 1, 4, 5, 8, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over deLarosiere (US 4416373) in view of Der Yuen (US 2641374).

With respect to claim 1, deLarosiere discloses a container (Figure 2:4) comprising an elongate cylindrical wall having a closed bottom end, and an opposed projecting neck portion end defining a liquid opening. When combined with a base cup (Figure 2:8), the container comprises an inwardly directed recessed portion for accommodating a neck portion end of an adjacent stacked similar container. The recessed portion includes at least one rib (Figure 5:30) extending therefrom for defining a space between the neck portion of the similar container and the bottom of the original container. This is disclosed in column 6, lines 21-65. The container is disclosed as a beverage bottle, but could intrinsically be used to provide a controlled environment for cell growth culturing. deLarosiere, however, discloses that the recessed portion includes a curved surface rather than a planar surface.

Der Yuen discloses a container (Figure 1:A) having a closed bottom end and an opposed projecting neck (Figure 1:B) defining a liquid opening. The closed bottom end includes an inwardly directed recessed portion (Figure 2:18) for accommodating a neck portion end of an adjacent stacked similar container (see Figure 3). The recessed portion includes a planar surface.

deLarosiere and Der Yuen are analogous art because they are from the same field of endeavor regarding containers are stackable.

At the time of the invention, it would have been obvious to include a planar surface within the recessed portion of the container disclosed by deLarosiere. A planar surface would have been desirable because it would have allowed one to more easily attach ribs to the bottom of the container. A planar surface would help insure that the

neck portion of the additional container rests flush on each of the provided ribs, and is not tilted. Differences in shape do not cause a claimed invention to be patentably distinct from the prior art, especially when the function of the device is not changed in an unexpected manner. See *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

With respect to claim 4, deLarosiere and Der Yuen disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above. In addition, deLarosiere teaches in Figure 5 and column 6, lines 29-32 that the rib is integral with the planar surface.

With respect to claim 5, deLarosiere and Der Yuen disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above. In addition, deLarosiere teaches in column 6, lines 47-65 that a plurality of supports (Figure 5:26) are provided with a plurality of side walls (Figure 5:32) that are used to guide the neck of one container to a seated position on the ribs of another container. Der Yuen also discloses a recessed portion with sidewalls in Figure 3.

With respect to claim 8, deLarosiere and Der Yuen disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above. In addition, it is apparent from Figure 5 that the recessed portion of deLarosiere's device defined by side walls (Figure 5:32) is generally frustoconical in shape.

With respect to claim 9, deLarosiere and Der Yuen disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above. In addition, deLarosiere's invention comprises a neck that includes integral external screw threads for receiving an internally screw threaded cap thereon. The bottle closure (Figure 1:10) is clearly depicted in the Figures as a screw threaded cap.

4) Claims 1, 3-5, 9, 10, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mussi (EP 0614967) in view of Land (US 3630849).

With respect to claims 1-5, Mussi discloses a stackable roller bottle comprising n elongate cylindrical wall having a closed bottom end including an inwardly directed recessed portion (Figure 1:42) that includes a planar surface and sidewalls. An opposed projecting neck portion end defining a liquid opening (Figure 1:24) is also provided. This is disclosed on page 3, lines 46-51. Page 3, line 57 to page 4, line 1 further teaches that the recessed portion is designed for accommodating the neck portion end of an adjacent stacked similar container. Mussi, however, does not expressly disclose that the planar surface of the recessed portion includes at least one rib extending therefrom for defining a space between the neck portion of the similar container and the planer surface.

Land discloses a cell culture container comprising a closed top end and a closed bottom end. The bottom end includes an inwardly directed recessed portion for accommodating the top portion of an adjacent stacked similar container. The recessed portion further includes a planar surface and sidewalls. A plurality of ribs is provided on

the container for defining a space between the top end of the similar container and the planar surface of the original container. This is disclosed in Figures 1 and 2, and in column 2, lines 29-42.

Mussi and Land are analogous art because they are from the same field of endeavor regarding stackable cell growth containers.

At the time of the invention, it would have been obvious to incorporate the ribs taught by Land upon the planar surface of the recessed portion of the roller bottle disclosed by Mussi. Land teaches in column 2, lines 39-42 that the ribs are beneficial because they define a space between two stacked containers that allows for increased air circulation between the opposing ends of the containers. In this way, effective and uniform temperature control of the containers can be accomplished. Furthermore, air circulation in and out of the containers is important because many cells require oxygen to grow. If ribs were not provided, it is likely that the neck portion of one of Mussi's containers and the recessed portion of another would combine to produce a tight fit that would not allow the diffusion of critical gasses to and from the top openings of the containers.

With respect to claims 9, 10, and 12, Mussi and Land disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above. In addition, Mussi teaches on page 3, lines 46-51 that the roller bottles are equipped with a neck that includes external screw threads and internally screw threaded caps (Figure 1:36). From

Figure 1, it is clear that the caps have a top surface and an annular outer skirt extending from the top surface to a bottom ledge.

5) Claims 2 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mussi (EP 0614967) in view of Land (US 3630849) as applied to claims 1 and 10, and further in view of Kayal (US 5695987).

Mussi and Land disclose the bottle assembly set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly disclose that the space between the two coupled containers permits gases to enter into and out of the liquid opening of the adjacent stacked container, or that the cap further includes a central orifice with an affixed gas permeable membrane.

Kayal discloses a cell culturing roller bottle (Figure 1:12) comprising a liquid opening that is covered by a screw cap. The cap includes a central orifice covered by a gas permeable membrane (Figure 3:56), and allows gases to enter into and out of the liquid opening. This is disclosed in column 1, lines 54-67.

Mussi, Land, and Kayal are analogous art because they are from the same field of endeavor regarding the use of capped bottles to contain a fluid.

At the time of the invention, it would have been obvious to alter the invention disclosed by Mussi and Land in order to allow the space between the two coupled containers to permit the entry of gases into the liquid opening of the adjacent, bottom container. The addition of gases to a culturing vessel is often essential because many microorganisms require certain gases such as oxygen to grow. Kayal discloses in

bottle caps comprising gas permeable membranes are an effective way to deliver critical gases to the culturing cells while preventing the passage of undesirable microorganisms and contaminants.

6) Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mussi (EP 0614967) in view of Land (US 3630849) as applied to claim 12, and further in view of Pedmo (US 6585123).

Mussi and Land disclose the roller bottle assembly set forth in claim 12 as set forth in the 35 U.S.C. 103 rejection above, however do not disclose that a plurality of ribs are provided that are equally spaced apart and radiate from a point proximal to the longitudinal axis of the container.

Pedmo discloses a bottle comprising an inwardly directed recessed portion at the bottom of the bottle. Ribs (Figure 5:34) are provided, which radiate from a point proximal to the longitudinal axis of the container toward the side wall of the recessed portion. A plurality of equally spaced apart ribs is provided. This is disclosed in column 2, lines 46-58.

Mussi, Land, and Pedmo are analogous art because they are from the same field of endeavor regarding the use of capped bottles to contain a fluid.

At the time of the invention, it would have been obvious to utilize a plurality of equally spaced apart, outwardly radiating ribs in the roller bottle assembly disclosed by Mussi and Land. In column 1, lines 11-20, Pedmo discloses that ribs constructed in this manner are beneficial because they improve the strength properties of the bottles, thus

Application/Control Number: 10/666,157 Page 11

Art Unit: 1744

enabling the bottles to withstand damage when physically struck. Pedmo additionally states that a plurality of ribs that radiate from the center of the bottle help the bottles withstand deformation during heat applications. Since incubation is sometimes completed under high temperatures, the utilization of ribs of this nature would be beneficial in the roller bottle assembly disclosed by Mussi and Land.

### Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Witt (US 4810652) and Berson (US 6720178) references disclose the state of the art regarding roller bottles.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on (571) 272-1226. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/666,157 Page 12

Art Unit: 1744

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**NAB** 

WILLIAM H. BEISNER PRIMARY EXAMINER GROUP